SC Pandemic Influenza Ethics Taskforce Steering Committee

Update of SC Region 6 Pan Flu Ethics Panel and National Pan Flu Ethics Summit 7.08

Covia Stanley, MD M Div
Phil Schneider, PhD
Tom Fabian, MD MPH
Robert Ball, MD, MPH

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Avian Influenza A-H5N1: Why We Should be More Concerned Now

1. A-H5N1 clade 2, subclade 1 now reported with occas. human-to-human transmission
2. A-H5N1 clade 2 now ~resistant to Tamiflu
3. Recent Indonesian mortality rate↑ >86%
4. Recent case of maternal-fetal deaths with A-H5N1 clade 2 found in mult. fetal tissues

Sources: 1&2:EID 9.07, 3:pandemicflu.gov→WHO, 4:MedPage 9.28.07

Pan Flu: Estimated Disease Impact in SC

- First wave would peak in ~6 wks in a community & last ≥2, ~3-4 months
- Cases statewide: 560,000 – 1,320,000 (first wave)
- Additional hospitalizations: 7,200 – 16,800 (normally no empty beds now in winter)
- **MD office visits: ~25 extra per doctor per day!**
- Flu deaths: 2,200 – 5,000 (close to double the usual number during the peak of the pandemic
- School children would be the biggest spreaders of infection

Source: DHEC- Tom Fabian, MD, MPH 10/06

Public Health Ethical Concerns

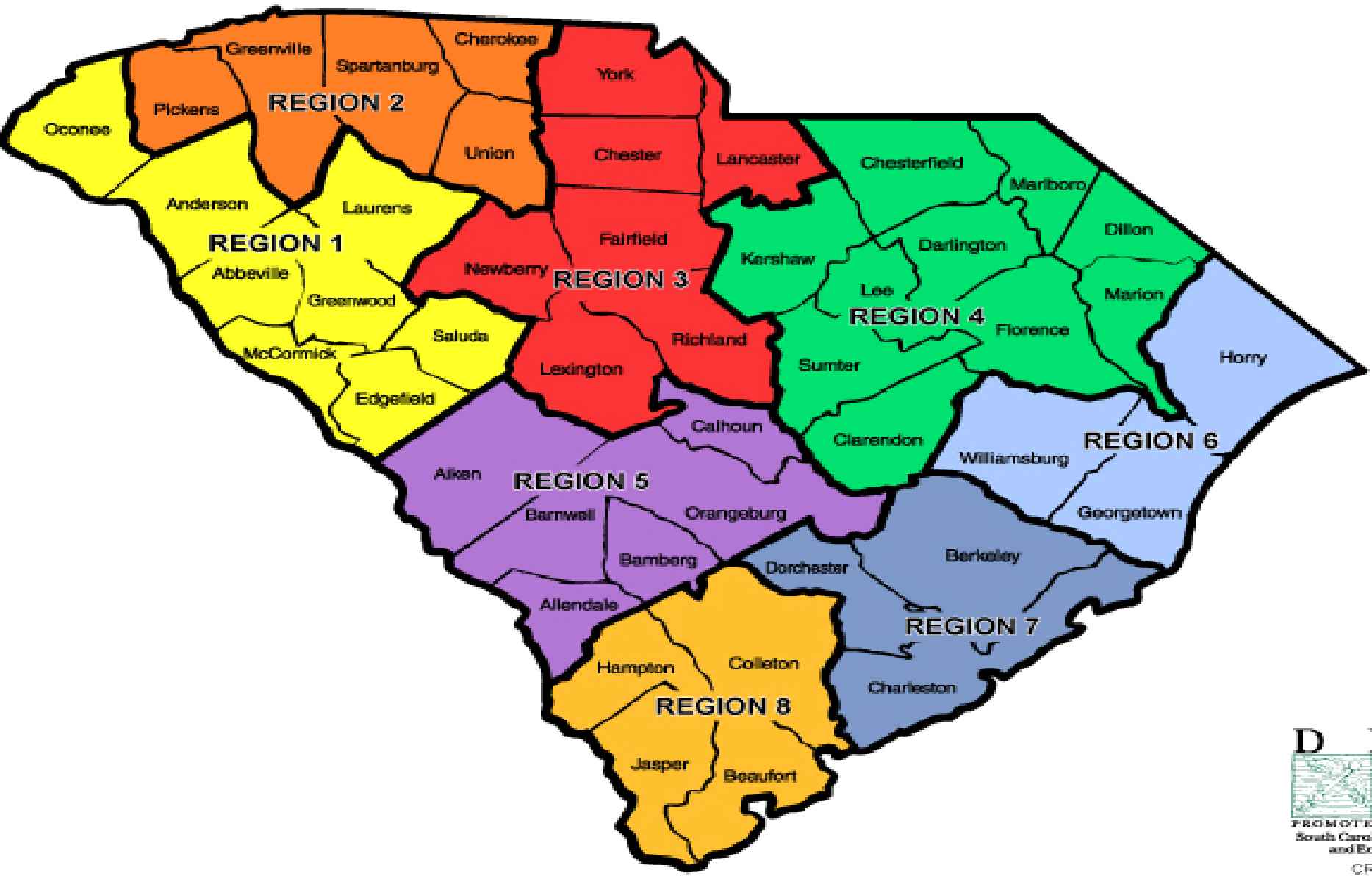
- Individual's right to privacy in Pt-physician relationship (ie, HIPAA, no governmental coercion)
- Individual's right to control their own body, medical decisions (ie, his/her destiny)
- Individual's right to freedom & liberty (ie, freedom of unrestricted movement & association)

- **vs. Distributive Justice: the fair distribution of limited goods & services (eg, hospital beds, ventilators, medicines, other medical care, etc)**

Pandemic Flu: Ethical Issues

- Allocating limited/ scarce resources (AVs, PPE, etc)
- Altered (alternative) standards of care (ICU, vents, etc)
- Protecting HCWs and Household contacts (Post-Exposure Prophylaxis [PEP], masks/ other PPE)
- Protecting the public: Isolation & Quarantine, etc?
- Medico-legal protection (provider indemnification)
- Informing the public: best messages? by whom?
- US Ethical Summit of States 7.08→ SC Taskforce 2008

DHEC Regions



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South Carolina Department of Health and Environmental Control

CR-000228 3/06

Region 6 Pan Flu Ethics Panel

PANEL GOALS

1. Recommend antiviral distribution priorities
2. Recommend vaccine distribution priorities
3. Recommend treatment triage priorities

ETHICS PANEL VALUES

- Minimize the rate of Pan Flu infection
- Maximize the number of Pan Flu survivors

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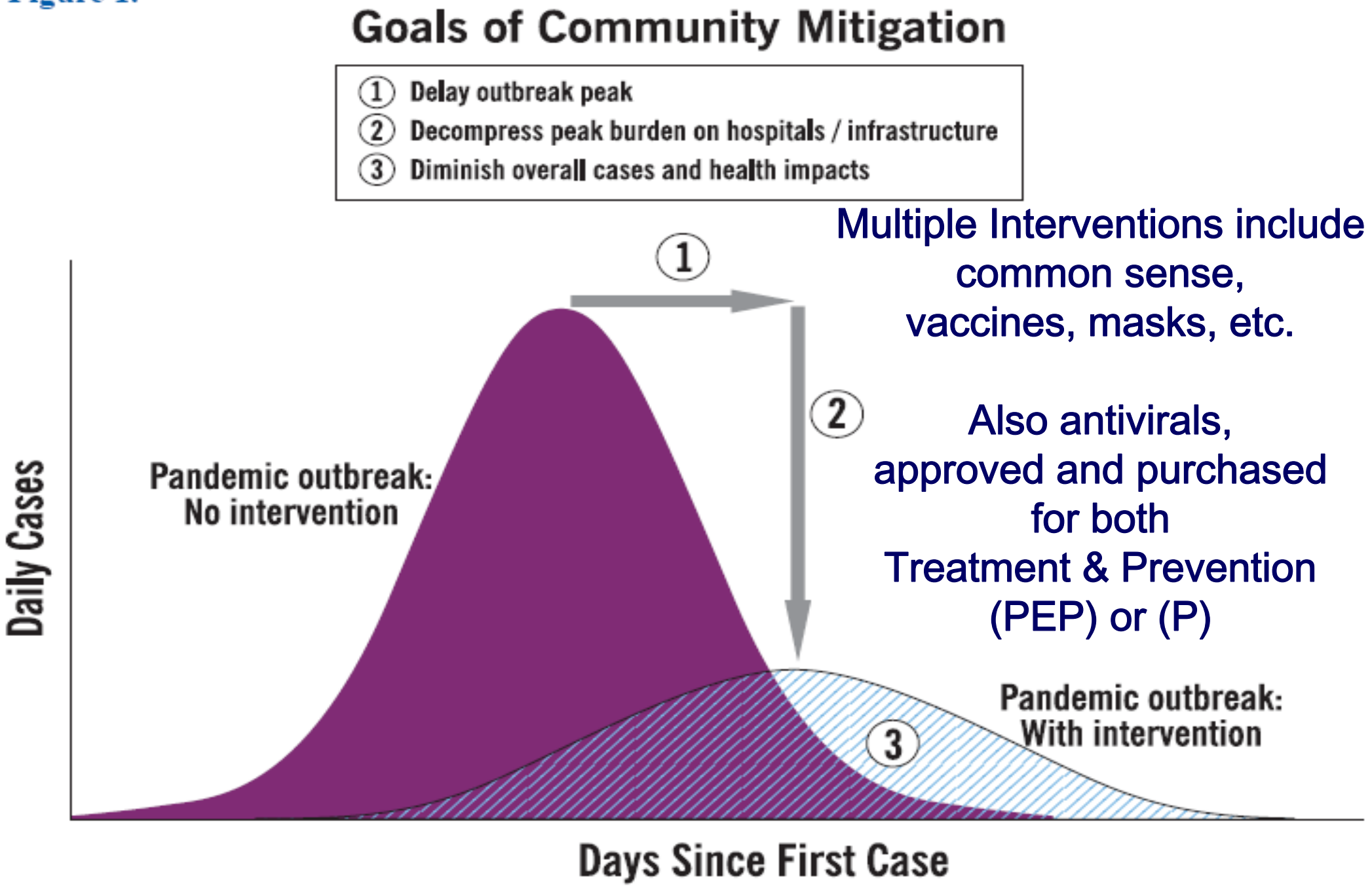
Figure 1.


Goals of Community Mitigation
1 Delay outbreak peak
2 Decompress peak burden on hospitals / infrastructure
3 Diminish overall cases and health impacts
Multiple Interventions include common sense, vaccines, masks, etc.
Also antivirals, approved and purchased for both Treatment & Prevention (PEP) or (P)
1
2
3
Pandemic outbreak: No intervention
Pandemic outbreak: With intervention
Daily Cases
Days Since First Case

Region 6 Pan Flu Ethics Panel

- **Substantive Values**
- **Individual Liberty Restrictions**

Movement, Contact, Quarantine, Vaccine, Antiviral, Respirator Recipient Priorities

- **Protection of the Public from Harm**

Reasons for public health measures

- **Proportionality of the above values**

Focus on actual risk and critical needs

- **Privacy Overrides**

Traditional right to privacy may become a subordinate moral value

- **Healthcare Workers' Duty to Provide Care**

Competing professional and personal obligations

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Region 6 Pan Flu Ethics Panel

- **Reciprocity for Healthcare Workers**

Social support for burden on patients, health care workers, and families

- **Equity in Various Healthcare Services**

Possible limits on emergency, necessary, or elective medical services

- **Trust between Clinicians, Patients, Public**

Decision makers must balance need, control, and stakeholder trust

- **Solidarity for Institutions and Nations**

Collaborative approaches that set aside national and institutional territoriality

- **Stewardship by Decision Makers**

Governance at all levels using coordinated, ethical, and reasonable decision making

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Pandemic Flu scenario 1

An elderly lady with Pan Flu is admitted with ARDS and other complications and put on the last ventilator in the ICU. Additional patients, many younger and less severely ill w/ more of a chance of survival come to the ED also needing ventilator support. Their physicians appeal to the lady's physician/ the hospital to remove her from the ventilator for use for one of their patients.

What does each participant do, and why?

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R. Ball, MD MPH

Pan Flu scenario 2

A family physician is swamped seeing Pan Flu patients, and the limited supply of Tamiflu locally is exhausted. His masks & other PPE are running low, and a vaccine is still months away. He and his staff are increasingly concerned about their safety. The large supply of Tamiflu distributed by DHEC has been restricted to "Treatment" only, but he wants to also use it also for HCW Prophylaxis.

What does each participant do, and why?

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Region 6 Pan Flu Ethics Panel

GOALS OF TREATMENT PRIORITIES

- Treating as many patients as possible
- Applying treatment resources to those most likely to benefit
- Involving hospital ethics committees in local priority decisions
- Establishing triage guidelines in advance with wide public communication during pandemic waves

Critical Care Triage Protocol: Canada

Triage code	Criteria	Action or priority
Blue	Exclusion criteria met or SOFA score > 11*	• Manage medically • Provide palliative care as needed • Discharge from critical care
Red	SOFA score ≤7 or single-organ failure	Highest priority
Yellow	SOFA score 8–11	Intermediate priority
Green	No significant organ failure	• Defer or discharge • Reassess as needed

Note: SOFA = Sequential Organ-Failure Assessment.
*If an exclusion criterion is met or the SOFA score is > 11 anytime from the initial assessment to 48 hours afterward, change the triage code to Blue and proceed as indicated.

Christian et al. CMAJ. 11.21.06

Fig 1: Prioritization tool used in triage protocol for the initial assessment of patients' needs for critical care during an influenza pandemic. See online Appendix 1 for the SOFA scoring criteria and online Appendix 2 for the complete prioritization tool, which includes details on reassessing patients at 48 and 120 hours (appendices are available at www.cmaj.ca/cgi/content/full/175/11/1377/DC1). See Box 2 for exclusion criteria.

Region 6 Pan Flu Ethics Panel

QUALIFICATIONS FOR ICU ADMISSION

- **Inclusion Criteria: Patients who may benefit from ICU care and who have a high priority of survival upon hospital discharge**

  (Includes influenza patients who require ventilator support or exhibit clinical evidence of shock and require treatment in an ICU setting.)

RESEARCH

Allocation of Ventilators in a Public Health Disaster

Tia Powell, MD, Kelly C. Christ, MHS, and Guthrie S. Birkhead, MD, MPH

ABSTRACT

Background: In a public health emergency, many more patients could require mechanical ventilators than can be accommodated.

Methods: To plan for such a crisis, the New York State Department of Health and the New York State Task Force on Life and the Law convened a workgroup to develop ethical and clinical guidelines for ventilator triage.

Results: The workgroup crafted an ethical framework including the following components: duty to care, duty to steward resources, duty to plan, distributive justice, and transparency. Incorporating the ethical framework, the clinical guidelines propose both withholding and withdrawing ventilators from patients with the highest probability of mortality to benefit patients with the highest likelihood of survival. Triage scores derive from the sepsis-related organ failure assessment system, which assigns points based on function in 6 basic medical domains. Triage may not be implemented by a facility without clear permission from public health authorities.

Conclusions: New York State released the draft guidelines for public comment, allowing for revision to reflect both community values and medical innovation. This ventilator triage system represents a radical shift from ordinary standards of care, and may serve as a model for allocating other scarce resources in disasters. (*Disaster Med Public Health Preparedness.* 2008;2:20–26)

Key Words: ventilator, triage, guideline, influenza, pandemic

Region 6 Pan Flu Ethics Panel

QUALIFICATIONS FOR ICU ADMISSION

- **Exclusion Criteria: Conditions that would rule out an ICU admission (e.g., 85 yrs old, end-stage organ failure, metastatic cancer, severe trauma or burns)**

(Patients that are likely to have a poor chance of survival with or without ICU care and would potentially tie up resources that could be used for patients who have a greater chance of recovery.)

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PRIORITIZATION FOR ICU ADMISSION

- **BLUE CODE: Patients not to be admitted as they do not meet the inclusion criteria – to be medically managed, provided palliative treatment, and discharged from the ICU**

- **RED CODE: Patients with the highest priority of ICU resources – sick enough to require the resource and whose outcome would be poor if they do not receive it and who are likely to recover with ICU care**

Region 6 Pan Flu Ethics Panel

PRIORITIZATION FOR ICU ADMISSION

- **YELLOW CODE: Patients will receive ICU care if available, but not at the expense of a RED CODE patient**

- **GREEN CODE: Patients deemed not ill enough to require ICU care**

Region 6 Pan Flu Ethics Panel

Altered standards of medical care during disasters

Emergency Department triage, ICU admission and discharge criteria, outpatient care, home care, palliative care

Prioritization (rationing) of limited/ scarce resources

Ventilators, bed space, antivirals, prophylactics, vaccines

Implementing and communicating necessary restrictions/ limitations on personal freedoms

Quarantine, isolation, school/church closures, social distancing

Medico-legal issues

State Board of Medical Examiners approval of altered standards of care,

Legislature: legislation needed providing narrowly circumscribed legal indemnification of triage officers and other medical providers implementing altered standards of care

Other: *Role of hospital ethics committees, mandating restrictions and requirements on medical staff privileges, volunteer healthcare workers, home care mechanisms*

R. Ball, MD MPH

Region 6 Pan Flu Ethics Panel

IMPLEMENTATION TIMELINE

(2008-2009) Convene a SC Pandemic Influenza Ethics TaskForce, hold regular meetings, draft guidelines of alternative standards of care and triage medical definitions

Involving SCMA, SC Board of Medical Examiners, SCHA, SCNA, SCBoN, EMD, EMS, universities, faith communities, citizens groups, print and broadcast media

(2009) Promulgate "Alternative Standards of Care During Disasters" to the State Medical Board for approval, to complement the SC Medical Practice Act

(2010) Development of a consensus bill for key legislators to introduce and pass in the General Assembly

Indemnification (not blanket immunity) for physicians, hospitals, and other providers implementing altered standards of care and rationing scarce resources

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Confronting the Ethics of

Pandemic INFLUENZA PLANNING

The 2008 Summit of the States

Indianapolis, Indiana

Indiana State Department of Health

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CENTER FOR BIOETHICS

Confronting the Ethics of Pandemic Influenza Planning:
Communiqué from the 2008 Summit of the States

Indianapolis, Indiana
July 14-15, 2008

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R. Ball, MD MPH

ETHICAL GUIDELINES in PANDEMIC INFLUENZA

Prepared by

Kathy Kinlaw and Robert Levine for the Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention[1]

Disclaimer: This document represents the recommendations of the Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention and does not necessarily represent Centers for Disease Control and Prevention policy. The document was reviewed and approved by the Advisory Committee to the Director on December 12, 2006 and approved for release by the Director of the Centers for Disease Control and Prevention, Dr. Julie Louise Gerberding, on February 15, 2007.

February 15, 2007

Pandemic Flu Preparedness: Ethical Issues and Recommendations to the Indiana State Department of Health

August 2007

INDIANA UNIVERSITY

Center for Bioethics

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R. Ball, MD MPH

Indiana State Department of Health

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CENTER FOR BIOETHICS

Confronting the Ethics of Pandemic Influenza Planning: Communiqué from the 2008 Summit of the States

Indianapolis, Indiana
July 14-15, 2008

Background

Like many public health emergencies, an outbreak of pandemic influenza will strain the ability of governments, communities, families, health care professionals and institutions to provide for the needs of people. Ethical issues will arise because critical decisions will inevitably challenge strongly held beliefs about personal autonomy, civil liberties and limitations on care. These ethical issues will be magnified because, in contrast with more localized emergencies (even devastating catastrophes like earthquakes or hurricanes), an outbreak of pandemic influenza will be nearly simultaneous across the entire country. Pandemic influenza will result in a prolonged scenario that does not lend itself to outside support or resources, placing an additional burden on local communities to be self-reliant.

Pan Flu Ethics Planning Summit

Summit Process

The Summit began with plenary sessions, during which new data from a national public opinion survey were presented and delegates were briefed by several participants on current challenges and best practices in their states. Summit delegates then broke into working groups to identify key ethical challenges that states and territories face in planning for pandemic influenza. In the final plenary, the delegates reached a consensus on the most important ethical issues and how to address them.

Summit Presentations & Breakout Sessions

- **Plenaries: Public Perceptions Survey, Best Practices (eg, NYS Ventilator Allocation, MN Vaccine Project, VA law), "Converting Good Ethics into Good Law", etc**
- **Workgroups: 1^0 topics=**

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Pan Flu Ethics Planning Summit

Outcomes

The Summit had two significant consensus outcomes:

1. Key Ethical Challenges that States and Territories Face in Planning for Pandemic Influenza

- Meeting the obligation to engage communities in planning and response to ensure fairness, transparency and participation
- Identifying and defining criteria for allocation of scarce health care and critical infrastructure resources
- Defining criteria and mechanisms for implementing altered standards and places of care
- Preventing exacerbation of disparities in access to care
- Balancing the rights and duties of health care and critical infrastructure workers
- Providing palliative care
- Meeting the needs of at-risk populations
- Assuring that community mitigation and containment strategies are appropriate for the severity of the pandemic
- Respecting cultural and religious practices in the face of mass fatalities

Pan Flu Ethics Planning Summit

2. Action Steps that States and Territories Should Take

Enhance Dialogue and Partnering

- Engage individuals, businesses and organizations in a dialogue about shared responsibilities
- Expand existing partnerships to include the Drug Enforcement Administration, the Food and Drug Administration, home care agencies, hospice providers and pharmacies to allow for robust palliative care in institutional and home settings
- Strengthen alliances and partnerships with professional health associations

Education and Training

- Train health care and critical infrastructure workers to identify, analyze and resolve ethical issues in pandemic response
- Foster education and collaboration among governmental agencies to marshal resources and coordinate shared responsibilities
- Develop suggested components and missions for local and state ethics committees.
- Establish a common website that provides a clearinghouse for ethics-related literature on pandemic influenza
- Create toolkits for local education, planning, partnerships and community engagement
- Establish a process, timeline and tools to reach consensus on key ethical challenges at local, state, regional and national levels

What other states are doing

Tom Fabian, MD MPH

VIRGINIA ACTS OF ASSEMBLY -- 2008 SESSION

CHAPTER 121

An Act to amend and reenact §§ 8.01-225.01, 8.01-581.1, 38.2-324, 44-146.16, 44-146.17, 44-146.18:1, 44-146.23, and 59.1-526 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 8.01-225.02, relating to health care provider liability protections.

[H 403]

Approved March 2, 2008

Be it enacted by the General Assembly of Virginia:

1. That §§ 8.01-225.01, 8.01-581.1, 38.2-324, 44-146.16, 44-146.17, 44-146.18:1, 44-146.23, and 59.1-526 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 8.01-225.02 as follows:

§ 8.01-225.01. Certain immunity for health care providers during disasters under specific circumstances.

A. In the absence of gross negligence or willful misconduct, any health care provider who responds to a ~~man made~~ disaster by delivering health care to persons injured in such ~~man made~~ disaster shall be immune from civil liability for any injury or wrongful death arising from abandonment by such health care provider of any person to whom such health care provider owes a duty to provide health care when (i) a state or local emergency has been or is subsequently declared; and (ii) the provider was unable to provide the requisite health care to the person to whom he owed such duty of care as a result of the provider's voluntary or mandatory response to the relevant ~~man made~~ disaster.

B. In the absence of gross negligence or willful misconduct, any hospital or other entity credentialing health care providers to deliver health care in response to a ~~man made~~ disaster shall be immune from civil liability for any cause of action arising out of such credentialing or granting of practice privileges if (i) a state or local emergency has been or is subsequently declared; and (ii) the hospital has followed procedures for such credentialing and granting of practice privileges that are consistent with the Joint Commission on Accreditation of Healthcare Organizations' standards for granting emergency practice privileges.

C. For the purposes of this section:

D H E

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D MPH

STAND ON GUARD FOR THEE

Ethical considerations in preparedness planning for pandemic influenza

November 2005

A report of the
University of Toronto Joint Centre for Bioethics
Pandemic Influenza Working Group

-FINAL DRAFT-

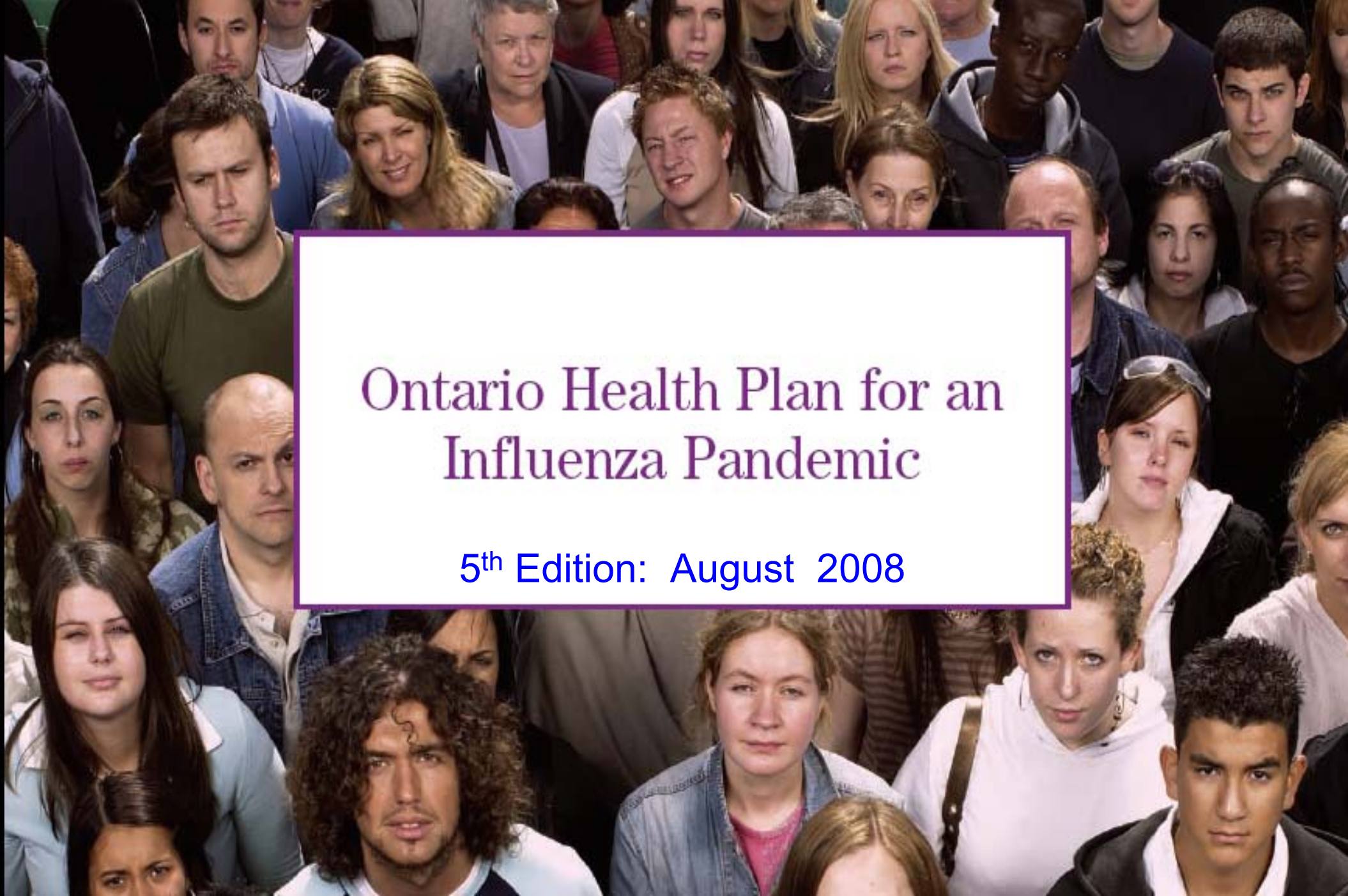
Criteria for Mechanical Ventilator Triage Following Proclamation of Mass-Casualty Respiratory Emergency

Alabama Department of Public Health
Healthcare Sector
Review Board
July 3, 2008

From early to later documents…

ADPH
EMERGENCY PREPAREDNESS
Alabama Department of Public Health

This document outlines a ventilator triage protocol intended for use only during a mass casualty event, proclaimed as a public health emergency by the Governor. It would be characterized by frequent, widespread cases of respiratory failure occurring in sufficient volume to quickly exhaust available mechanical ventilator resources. One example might include, not exclusively, a virulently aggressive form of pandemic influenza. Such pandemics have occurred in the past and could recur, stressing healthcare systems to their breaking points.



Ontario Health Plan for an Influenza Pandemic

5th Edition: August 2008

Pandemic Influenza

Get Informed...Be Prepared

A newsletter for Minnesota organizations preparing for a possible influenza pandemic.

Jan/Feb 2008
Vol. 3. No. 1

Focus on pandemic planning efforts

This edition of the newsletter highlights some of the remarkable pandemic planning activities occurring across the state that have really picked up momentum lately.

These activities range from the ongoing work of the Minnesota Pandemic Ethics Project (as they come close to the end of Phase I of the project) to the unique planning occurring within the Mortuary Science Section here at MDH. Additionally, the Minnesota Department of Education provides an update on the collaborative work they have embarked on lately.

Minnesota Pandemic Ethics Project Update

In 2007 the Minnesota Department of Health (MDH) contracted with ethicists from the Minnesota Center for Health Care Ethics and the University of Minnesota's Center for Bioethics to develop and lead the Minnesota Pandemic Ethics Project.

The project's primary goal is to develop ethical frameworks for how Minnesota should ration critical health-related resources in a severe influenza pandemic. To that end, a community-based resource allocation panel, expert work groups, and a protocol committee (together comprising more than 100 people) were formed as part of this project.

The project addresses the allocation of five health-related resources that are anticipated to be useful, but scarce in a severe pandemic: antiviral medications, N95 respirators, surgical masks, pandemic vaccines, and mechanical ventilators. How best to ration them from a statewide perspective during a global public health disaster raises novel ethical issues.

Stockpiling Solutions:

North Carolina's Ethical Guidelines for an Influenza Pandemic

April 2007

North Carolina Institute of Medicine

In collaboration with the North Carolina Department of Health and Human Services, Division of Public Health

Funded by the North Carolina Department of Health and Human Services, Division of Public Health

ETHICS

Planning & Assessment Tool

A Healthcare Guide for Pandemic Flu Planning

PLANNING TODAY FOR A PANDEMIC TOMORROW

July 2008

NJHA
NEW JERSEY HOSPITAL ASSOCIATION

COMMENTARY

NC Medical Journal 1-2.07
http://www.ncmedicaljournal.com/jan-feb-07/toc0207.shtml

Ethical Guidelines for an Influenza Pandemic

E. Kiernan McGorty, JD, MA; Leah Devlin, DDS, MPH; Rosemarie Tong, PhD; Natasha Harrison; Mark Holmes, PhD; and Pam Silberman, JD, DrPH

COMMENTARY

Likely Ethical, Legal, and Professional Challenges Physicians will Face During an Influenza Pandemic

Janelle A. Rhyne, MD

Pandemic Influenza:
The Critical Issues and North Carolina's Preparedness Plan

Jeffrey P. Engel, MD

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Pan Flu: Major Barriers to Medical Implementation of ASC

Robert Ball, MD MPH

- Need for statewide professional and public consensus on various elements

- Need for legal indemnification of providers when morbidity & mortality events trigger complaints, lawsuits

NEJM 358:1, 1.3.08

Perspective
JANUARY 3, 2008

Dr. Pou and the Hurricane — Implications for Patient Care during Disasters

Susan Okie, M.D.

During the flood after Hurricane Katrina in August 2005, health care providers in marooned New Orleans hospitals worked in almost unimaginably difficult conditions while awaiting rescue.

Nowhere was the situation more desperate than at Memorial Medical Center, where for 4 days a small staff struggled to care for critically ill patients in a dark building with no electric power, no fresh water, a flooded first floor, a nonfunctional sanitation system, and an interior temperature above 100°F.

Dr. Anna Maria Pou, a cancer surgeon on the faculty of Louisiana State University School of Medicine, was supervising residents at Memorial when Katrina hit on Monday, August 29, and she remained at the hospital after the storm. Pou, 51, is a New Orleans native whom colleagues describe as a dedicated, hard-working physician who, though physically small, "had a huge presence."[1] At least 34 patients died at Memorial during and after the storm, and shortly thereafter, media reports began to suggest that some had been euthanized. In July 2006, Louisiana's attorney general, Charles Foti, shocked the country by arresting Pou and two nurses, accusing them of administering morphine and midazolam to kill four elderly patients on September 1, 2005, the day patient evacuation was completed. In a television interview aired in September 2006, Pou denied the accusation, stating, "I did not murder those patients. . . . I do not believe in euthanasia. I don't think it's anyone's decision to make when a patient dies. However, what I do believe in is comfort care, and that means that we ensure that they do not suffer pain."

A grand jury considered possible murder charges in the deaths of these four patients plus five others on the same floor, and the attorney general agreed not to pursue charges against the nurses in exchange for their testimony against Pou. Many New Orleans residents rallied to Pou's support, calling her a hero for remaining on duty when other doctors had fled, and numerous medical organizations issued statements in her defense. This past August, the grand jury refused to indict Pou, but she still faces three civil suits that have been brought by rela-

it possible they were given an overdose? Yes. But it's also just as possible that they were suffering, that she came through and gave some kind of dose that she thought was appropriate." Quill

believes "she was trying to do the right thing in an awful situation and was doing the best she could."

One lesson of Pou's experience is the need for community discussions about what care should be provided during a disaster that strains medical resources, said Marianne Matzo, a professor of nursing at the University of Oklahoma and coauthor of a report on the subject.[5] Katrina left many survivors while disabling a city's health care network; another storm, a disastrous earthquake, or a severe epidemic could create a similar scenario. "There are people who, as a result of the disaster, are steps away from death," Matzo said. "As a community we have to say, what are we going to do if we don't have the resources" to evacuate or treat everyone?

But hospitals and communities are unlikely to confront such questions without leadership from government, medical schools, and medical specialty organizations, because discussion of changing standards of care involves "not only liability but political risks," said Craig Llewellyn, professor emeritus of military and emergency medicine at the Uniformed Services University of the Health Sciences (USUHS). Currently, he said, governors can declare a state of emergency during disasters, "suspending some of the normal standards without giving any idea of what the alternative standards ought to be," and medical professionals who care for disaster victims are not protected from lawsuits or criminal prosecution by such declarations. Pou's case has triggered discussion about whether laws are needed to indemnify such volunteers.

Pou argues that "the conditions faced were similar to battlefield conditions" and that civilian medical training does not prepare physicians for such circumstances: "There's nothing that teaches reverse triage, military evacuation strategies, or how to prepare oneself for the feelings of helplessness and sorrow that come when there is little to do for a patient based on lack of resources." However, USUHS has experience training medical students to make triage decisions in such conditions: they participate in exercises in which the demand for treatment exceeds available resources, with volunteers playing the parts of injured soldiers, civilians, enemy prisoners, and so on. "You have to prioritize who gets on the operating table or who gets the one vacant litter position on the only helicopter you're liable to see for the next 4 hours," Llewellyn said, which forces students to confront "difficult clinical, ethical, and moral issues." Without a similar focus on altered standards of care in extreme situations in civilian medicine, Llewellyn said, doctors will face disasters unprepared, and citizens will be unaware of the choices that may be required. But with expanded training and public debate about triage, communication, and decision making when resources are limited, caregivers may be better equipped for the kind of ordeal that Pou and her colleagues faced after the deluge.

Dr. Okie is a national correspondent for the *Journal*.

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5. Phillips SJ, Knebel A, eds. Mass medical care with scarce resources: a community planning guide. Rockville, MD: Agency for Healthcare Research and Quality, February 2007. (AHRQ publication no. 07-0001.) (Accessed December 12, 2007, at http://www.ahrq.gov/research/mce/.)

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 1 - I-05

Subject: The Use of Quarantine and Isolation as Public Health Interventions

Presented by: Priscilla Ray, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws (Charles J. Hickey, MD, Chair)

RECOMMENDATIONS

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

Quarantine and isolation to protect the population's health potentially conflict with the individual rights of liberty and self-determination. The medical profession, in collaboration with public health colleagues, must take an active role in ensuring that those interventions are based on science and are applied according to certain ethical considerations.

(1) To this end, the medical profession should:

(a) seek an appropriate balance of public needs and individual restraints so that quarantine and isolation use the least restrictive measures available that will minimize negative effects on the community through disease control while providing protections for individual rights;

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY SEPTEMBER 2007, VOL. 28, NO. 9

REVIEW ARTICLE

The Ethics of Infection Control: Philosophical Frameworks

Charles S. Bryan, MD; Theresa J. Call, BS; Kevin C. Elliott, PhD

Recent developments that are relevant to the ethics of infection control include the patient safety movement, the appearance of new diseases (notably, severe acute respiratory syndrome) that pose threats to healthcare workers, data confirming the suspicion that infection control measures such as isolation may compromise patient care, and, in philosophy, renewed interest in virtue ethics and communitarianism. We review general ethical frameworks and relevant vocabulary for infection control practitioners and hospital epidemiologists. Frameworks for the ethics of infection control resemble those of public health more than those of clinical medicine but embrace elements of both. The optimum framework, we suggest, takes into account a virtue-based communitarianism. The virtue ethics movement stresses the need to consider not only rules and outcomes but also the character of the individual(s) involved. Communitarianism emphasizes the well-being and values of local communities, best determined by shared, democratic decision making among stakeholders. Brief discussions of 15 consecutive cases illustrate the extent to which the daily practice of infection control poses problems heavily freighted with ethical overtones.

Infect Control Hosp Epidemiol 2007; 28:1077-1084

Communitarianism is, in brief, an emerging ethical and political philosophy, closely allied with virtue ethics, whereby stakeholders formulate policies based on their shared vision of the optimum society. We should emphasize "shared," because communitarianism functions best in the context of a participatory (not merely representative) democracy. Com-

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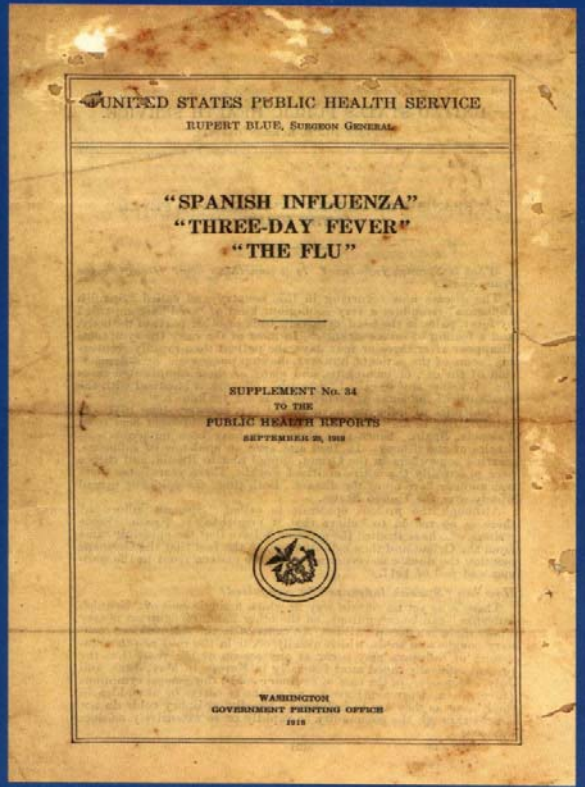

Symposium Issue: Seasonal and Pandemic Influenza

Pandemic Influenza and Lessons from History

Pandemic Flu in the Doctor's Office

Pandemic Flu: Who Will Care?

South Carolina Prepares for Pandemic Influenza

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Pandemic Flu: worst case scenario

- Hospitals/ health care providers overwhelmed
- Routine medical care is limited/ unavailable
- Accumulating #s of dying patients (creates fear)
- Many non-essential services/ businesses close
- Essential services (gov't.,utilities, etc.) marginal
- Supply of food, goods, materials reduced
- Public concern→anxiety (hope not→panic/chaos)

DHEC
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Pandemic Influenza: mitigation…

- Early aggressive medical care: isolation, testing, & Tx of ILI cases/"suspect" (test results: PCR~1d./ culture ~1 wk.~strain)
- Other: quarantine/ PEP of close contacts (Household & HCWs). Q.day Pre-Exposure Prophylaxis (P)? [supplies QNS]
- Aggressive common-sense Inf. Control, hygiene campaigns (cough etiquette, handwashing, social distancing, etc.)
- Closure of many schools & optional social large public gatherings. Shelter-in-place, telecommuting if possible.
- ? mass SARS-like screenings at airports, borders, and even border closings- probably unrealistic, but politicians…
- Some antivirals, vaccines likely available to supplement these.

P.H. Decision-making Processes

- 1º Individuals involved must be multi-disciplinary, learned & respected professionals of high moral character, known in the larger community, & have no vested (economic) interests. DHEC should lead.

- Process must be as transparent as possible and include as many stakeholders as reasonably poss.

- Process should begin PRIOR to crisis/ disaster, use ICS during crisis, and include post-crisis repair

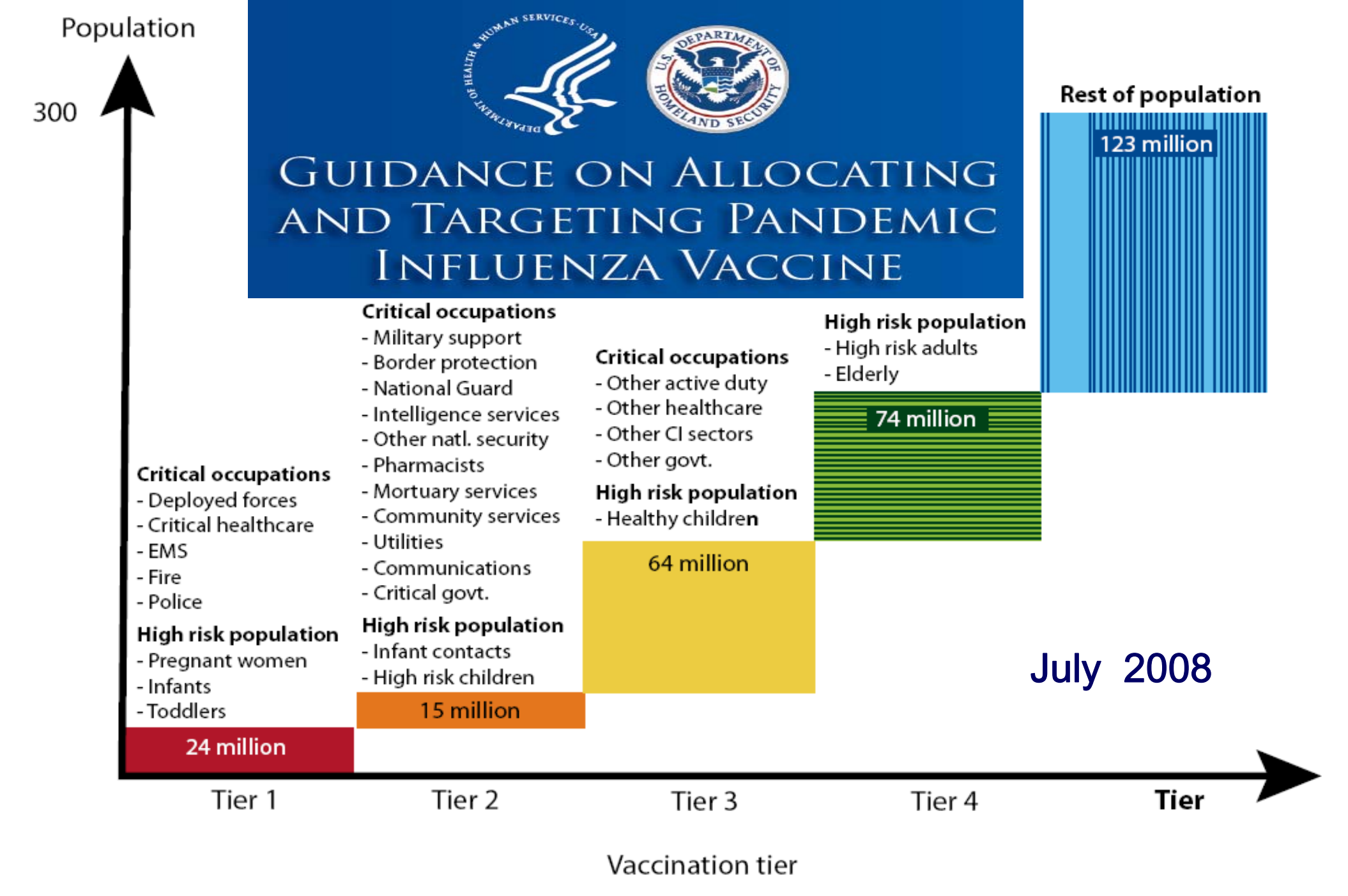
ACIP/NVAC proposed vaccine priority group recommendations

Q: if/how much the currently-stockpiled A-H5N1 vaccine will match the next Pan Flu strain ?

Novel virus→ ~6-7 mos. to develop a novel vaccine

1A	Vaccine and antiviral manufacturers; HCW ←	(9M)
1B	Highest risk	(16M)
1C	Pregnant women HH contacts*	(11M)
1D	PH emergency workers Key government officials	(?)
2A	High risk	(58M)
2b	Public safety and other critical infrastructure	(9M)
3	Other key health decision makers; funeral services	(?)
4	Healthy children and adults	(180M)

* Of severely immunocompromised and infants <6m


Population
300
GUIDANCE ON ALLOCATING AND TARGETING PANDEMIC INFLUENZA VACCINE
Critical occupations
- Deployed forces
- Critical healthcare
- EMS
- Fire
- Police
High risk population
- Pregnant women
- Infants
- Toddlers
24 million
Critical occupations
- Military support
- Border protection
- National Guard
- Intelligence services
- Other natl. security
- Pharmacists
- Mortuary services
- Community services
- Utilities
- Communications
- Critical govt.
High risk population
- Infant contacts
- High risk children
15 million
Critical occupations
- Other active duty
- Other healthcare
- Other CI sectors
- Other govt.
High risk population
- Healthy children
64 million
High risk population
- High risk adults
- Elderly
74 million
Rest of population
123 million
July 2008
Tier 1
Tier 2
Tier 3
Tier 4
Tier
Vaccination tier

Pan Flu: SNS Antiviral Allocation: Tx (T) of Patients with ILI

Table D–2: Antiviral Drug Priority Group Recommendations*

National Plan, Appendix D (Nov. '05)

	Group	Estimated population (millions)	Strategy**	# Courses (millions)		Rationale
				For target group	Cumulative	
1	Patients admitted to hospital***	10.0	T	7.5	7.5	Consistent with medical practice and ethics to treat those with serious illness and who are most likely to die
2	Health care workers (HCW) with direct patient contact and emergency medical service (EMS) providers[4]	9.2	T	2.4	9.9	Healthcare workers are required for quality medical care. There is little surge capacity among healthcare sector personnel to meet increased demand.
3	Highest risk outpatients—immunocompromised persons and pregnant women	2.5	T	0.7	10.6	Groups at greatest risk of hospitalization and death; immunocompromised cannot be protected by vaccination.
4	Pandemic health responders (public health, vaccinators, vaccine and antiviral manufacturers), public safety (police, fire, corrections), and government decision-makers	3.3	T	0.9	11.5	Groups are critical for an effective public health response to a pandemic.
5	Increased risk outpatients—young children 12-23 months old, persons ≥ 65 yrs old, and persons with underlying medical conditions	85.5	T	22.4	33.9	Groups are at high risk for hospitalization and death.

T = Tx = 1 cap. bid x 5 d.

pandemicflu.gov→ federal plans→ HHS Pan Flu Strategic Plan

Pan Flu: SNS Antiviral Allocation: PEP, P,& T of Patients & HCWs

Table D–2: Antiviral Drug Priority Group Recommendations*

National Plan, Appendix D (11-05)

	Group	Estimated population (millions)	Strategy**	# Courses (millions)		Rationale
				For target group	Cumulative	
6	Outbreak response in nursing homes and other residential settings	NA	PEP	2.0	35.9	Treatment of patients and prophylaxis of contacts is effective in stopping outbreaks; vaccination priorities do not include nursing home residents
7	HCWs in emergency departments, intensive care units, dialysis centers, and EMS providers	1.2	P	4.8	40.7	These groups are most critical to an effective healthcare response and have limited surge capacity. Prophylaxis will
8	Pandemic societal responders (e.g., critical infrastructure groups as defined in the vaccine priorities) and HCW without direct patient contact	10.2	T	2.7	43.4	Infrastructure groups that have impact on maintaining health, implementing a pandemic response, and maintaining societal functions
9	Other outpatients	180	T	47.3	90.7	Includes others who develop influenza and do not fall within the above groups
10	Highest risk outpatients	2.5	P	10.0	100.7	Prevents illness in the highest risk groups for hospitalization and death.
11	Other HCWs with direct patient contact	8.0	P	32.0	132.7	Prevention would best reduce absenteeism [illegible]

PEP or P = 1 cap. qd x ? d.

These groups are NOT mutually exclusive or timeline-defined!

pandemicflu.gov→ federal plans→ HHS Pan Flu Strategic Plan

DHHS draft Antiviral Drug Use Strategies during Pan Flu 11.6.07

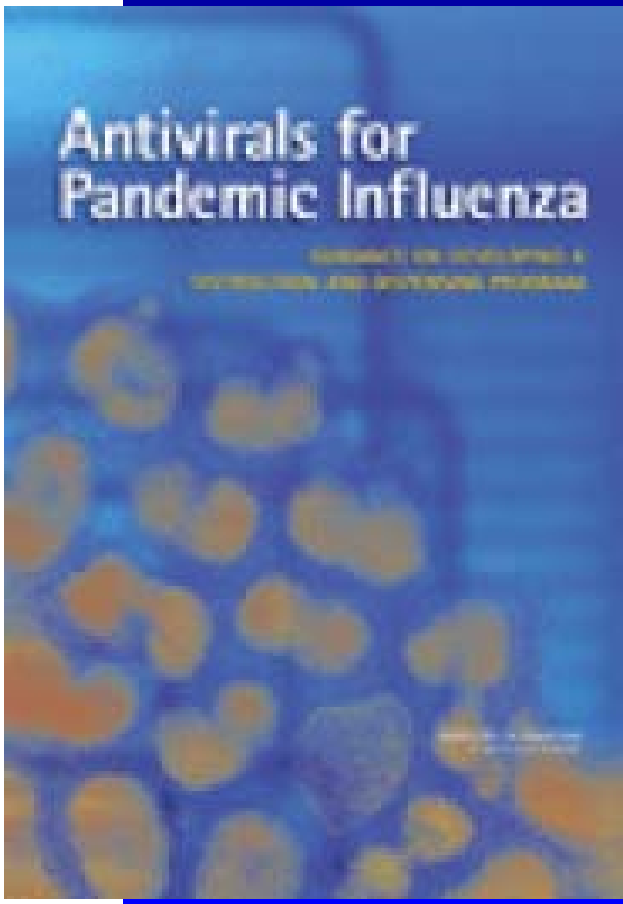
Proposed Guidance on Antiviral Drug Use Strategies during an Influenza Pandemic

Summary

Antiviral drug use will be an important component of a pandemic influenza response. While current antiviral drug use strategies and stockpiled assets are targeted primarily for treatment of persons with pandemic illness, expanded antiviral drug production has allowed new strategies to be considered. An interagency working group, with representatives from State, local and tribal public health agencies, considered scientific issues, ethics and values, and perspectives of stakeholders in developing draft guidance on antiviral use strategies and stockpiling.

This document provides guidance for the use of influenza antiviral medications assuming that effective community mitigation measures will reduce pandemic illness by one-half. Because of uncertainty regarding pandemic vaccine timing and supply, no assumptions are made regarding vaccine use impacts.

Draft guidance on antiviral use was based on goals of the U.S. national pandemic response which are to slow the spread of pandemic disease, reduce impacts on health, and minimize societal and economic disruption. The working group recommends the



Pan Flu & Health Care WorkForce

- Where will you be? What will you be doing?
- Is your rationale ethical and balanced?
- What are your personal responsibilities to you but also to your family?
- What are your professional responsibilities to your patients and your community?
- Must you put yourself in harm's way?

Pan Flu: reprioritizing ED & MDs

- **Many surgical & medical specialists will see a ↓ in patient load:** Q: how to wisely utilize these physicians time & talents?
- **EDs will see ↑caseloads:** Q: how to provide relief for already slammed EDs?
- **Why not …:** arrangements/ MOAs for local physicians to "cover" EDs while ED docs become Pan Flu triage specialists?

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